



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM:

To: Carmen Rodia

From: Jennifer Urbanski, Ph.D.

A handwritten signature in black ink, appearing to read "J. Urbanski", is written over the "From:" line.

Date: 1/20/15

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD

DP barcode: 419844

Decision no.: 489559

Submission no: 949994

Action code: R170

Product Name: RMI-2-11-B

EPA Reg. No or File Symbol: 270-379

Formulation Type: feedthrough

Ingredients statement from the label: 8% diflubenzuron (108201)

Application rate(s) of product and each active ingredient: Dependent on swine weight; 0.2-0.3 mg diflubenzuron/kg/day

I. Action Requested: Determine if the data submitted to support the addition of flies for swine

II. MRID Summary (DER attached):

49353402

(1) GLP or non-GLP? Non-GLP

(2) State the purpose and briefly summarize the methods and results: Swine were fed the test product at rates of 0.15 mg, 0.2 mg and 0.3 mg of diflubenzuron/kg of body weight/day (4 swine per treatment, plus 4 untreated swine as a control). Three samples of manure were collected from each swine every day for 9 days. Twenty-five house fly larvae were placed on the manure in each cup for each day and held there for ~3 weeks. Adult emergence was recorded and efficacy for the treatments was calculated as treatment fly emergence compared to control fly emergence. By day 2, there was greater than 90% for the 0.2 and 0.3mg treatments while the 0.1mg treatment did not result in <90% through 9 days. While control emergence seemed low, the treatment emergence was close to 0; in addition, the registrant provided a reference indicating that low emergence is not uncommon for fly larvae and may be a result of moisture content of manure (Fatchurochim, S. et al. 1989. Filth fly (Diptera) oviposition and larval development in poultry manure of various moisture levels. J. Entomol. Sci. 24(2): 224-231).

(3) State conclusions as they relate to study results following your review of the primary efficacy review and the study materials: Given the extremely low level of treatment emergence and the registrant-provided explanation for the control emergence, the data submitted support the use of the product to control house flies for swine at a rate of 0.2-0.3 mg/kg/day.

(4) Is the MRID acceptable? Acceptable.

III. RECOMMENDATIONS:

- 1) Data only support the control of house flies at a rate of 0.2-0.3 mg/kg/day for swine. Therefore, any marketing claims related to flies on swine must specify "house flies". General fly claims, and claims against other species of fly, for swine are not supported by the submitted data.

DATA EVALUATION RECORD

[EPA Primary Reviewer's Name]

STUDY TYPE:	OCSPP GUIDELINE NO: Not given
MRID:	493534-02. Pitzer, J.B. Final Report on Efficacy of Diflubenzuron Against Pest Flies Developing in Manure from Treated Animals 2. February 26, 2013.
DP BARCODE:	419844
DECISION NO:	489559
SUBMISSION NO:	949994
SPONSOR:	Casey S. White Farnam Companies, Inc. (d.b.a. Central Life Sciences) 301 W. Osborn Road Phoenix, Arizona 85013
TESTING FACILITY:	New Mexico State University Veterinary Entomology Research Laboratory 3115 Aggie Rodeo Dr. Las Cruces, New Mexico 88011
STUDY DIRECTOR:	Dr. Jimmy B. Pitzer
SUBMITTER:	Steven R. Spaulding Senior Director, Regulatory Affairs
STUDY COMPLETED:	13/12/2012
CONFIDENTIALITY CLAIMS:	None
GOOD LABORATORY PRACTICE:	This study was not conducted according to the principles of Good Laboratory Practices and is not in compliance with the United States Environmental Protection Agency's Federal Insecticide, Fungicide and Rodenticide Act, Good Laboratory Practice Regulations, 40 CFR Part 160, current edition.

TEST MATERIAL:	PRODUCT NAME: RMI-2011-B EPA REGISTRATION NUMBER OR FILE SYMBOL: 270-379 ACTIVE INGREDIENT NAME: Diflubenzuron CHEMICAL NAME: Not given A.I. %: 8% PC CODE: 108201 CAS NO.: 35367-38-5 FORMULATION TYPE: Applied in animal feed concentrate PRODUCT APPLICATION RATE(S) : For mixing 0.20 mg/kg/day : $CWT \div \text{consumption (lbs)} \times 0.5 = \text{lbs of RMI-2011-B per ton of product being manufactured}$; for mixing 0.30 mg/kg/day: $CWT \div \text{consumption (lbs)} \times 0.75 = \text{lbs of RMI-2011-B per ton of product being manufactured}$ ACTIVE INGREDIENT APPLICATION RATE(S)g/m ² : Not given
PROPOSED LABEL MARKETING CLAIMS:	Prevents the emergence of house flies from manure of treated swine

STUDY REVIEW

Purpose: The purpose of this experiment was to determine the ability of diflubenzuron to inhibit house fly development in feces collected from swine fed a 0.67% diflubenzuron formulation at net rates of 0.15 mg, 0.2 mg and 0.3 mg of diflubenzuron/kg of body weight/day.

MATERIALS AND METHODS

Test Location: Las Cruces, New Mexico

Test Material(s): RMI-2011-C, lot #0.67BR002, a dry mix of feed ingredients and active Ingredient (0.67% diflubenzuron)

Test Species Name, Life Stage, Sex and Age: House fly, *Musca domestica* L

Describe test containers, chambers and/or apparatus (include site description and location) and how experiment was conducted:

5.1 Experimental Design:

The experimental design includes four groups, with test animals assigned to the groups according to the following table.

Group Designation	Treatment	# of Animals
TREATMENT 1	0.15 mg of diflubenzuron/kg of body weight/day	4
TREATMENT 2	0.20 mg of diflubenzuron/kg of body weight/day	4
TREATMENT 3	0.30 mg of diflubenzuron/kg of body weight/day	4
CONTROL	untreated control group	4

5.2 Assignment to Treatment:

Test animals were randomly assigned to treatment groups by a lottery process; however, the number of females and castrated males were evenly distributed across all treatment groups. All unique animal identification numbers of females were placed into a container and drawn in groups of three. The first three female animal numbers drawn were assigned to TREATMENT 1; the second three female animal numbers drawn were assigned to TREATMENT 2 and so on, until all twelve female animals were assigned to the four treatment groups. All unique animal identification numbers of castrated males were placed into a container and drawn. The first castrated animal number drawn was assigned to TREATMENT 1; the second castrated male animal number drawn was assigned to TREATMENT 2 and so on, until all four castrated male animals were assigned to the four treatment groups.

5.3 Acclimation Period:

Test animals were housed in the test housing beginning on Day -4, and remained there until the end of the 10-day test material feeding and feces collection schedule.

6.0 Procedures:

6.1 Treatment of Animals:

All TREATMENT 1, TREATMENT 2, and TREATMENT 3 animals were fed the test substance for the first nine days of the treatment period (Days 0-8). Each morning, each animal received 0.5 pounds of a NMSU standard concentrate ration top-dressed with the test substance at the rate required for the given treatment group according to the table in 5.1. Dosage calculations and feeding records were recorded each day for each animal on the Animal Feeding Record Form (Appendix 14.7). Animals were allowed sufficient time to consume all of the top-dressing and feed before given their remaining morning allotment of the same NMSU standard concentrate diet.

All CONTROL animals were similarly fed, except that the NMSU standard concentrate diet was not top-dressed with the test substance.

6.2 Manure Collection:

Manure was collected each morning (prior to feeding) from the visibly freshest feces in each animal's pen beginning on Day 0 (i.e. before first treatment) and continuing through Day 9. If a sufficient amount of fresh feces was not available in the pen, multiple feces collections were made

for that animal on that day and combined to provide the needed amount for bioassay.

Beginning on Day 0 and continuing through Day 9, a minimum of 300 g of feces was collected from each animal. Feces from each animal were placed into Zip Loc gallon size freezer bags. Each freezer bag was labeled with a Sharpie® permanent ink pen on the bag's white label area as to collection date, animal number, treatment group and study day, and frozen for a minimum of 48 hours to kill any arthropod fauna that had infested the feces before collection. The feces were held frozen for a maximum of two months while larval bioassays are prepared.

6.3 Bioassays:

For each pig on each collection day, three bioassay cups were prepared using the feces on a given collection day. Therefore, 16 pigs x 3 cups x 10 days generated a total matrix of 480 total grow-out cups. Feces bags were removed from the freezer and allowed to thaw for 1 day prior to use in fly bioassays. The feces sample was mixed thoroughly by hand to ensure a homogeneous sample mixture. Approximately 50 g of feces were placed in each plastic bioassay cup (45 ml) and marked according to animal identification, treatment group, and study day. House fly larvae (less than 24 hours old) were collected, and 25 larvae were placed in each cup containing a feces sample. Bioassay cups were placed into a larger 120 ml plastic cup, and covered with fabric to prevent adult fly escape, but allow air exchange. All cups were held at 80 °F, 12:12 LD, and approximately 40% RH, for a period of 3 weeks.

When possible, all fly bioassays were conducted concurrently to obviate or at least minimize environmental differences that might introduce bias. If all samples could not be prepared on the same day, the samples were divided by study day(s) such that all three TREATMENT groups were run alongside the CONTROL group for the same day(s), with bioassays staggered. Fly infestation and emergence data was recorded on the Fly Emergence Data Collection Form (Appendix 14.8).

List the treatments including untreated control (express application rate as g/m²): 0.15, 0.20, and 0.30 mg of 0.67% diflubenzuron per kg of body weight per day; untreated control

Number of replicates per treatment: 120

Number of individuals per replicate: 25

Length of exposure to treatment (time in seconds, minutes or hours): 3 weeks

Were tested specimens transferred to clean containers? NA

Experimental conditions (state relative humidity, temperature, and photoperiod): 80° F, 40% RH, and 12 hr LD

Data or endpoints collected/recorded: Fly emergence

Data analysis:

The following equation was used to calculate percent efficacy for each of the two TREATMENT groups. “AAFE” stands for “average adult fly emergence,” the averages being of individual emergence data for each of the four animals (12 cups) within the specific group in question.

$$\% \text{ Efficacy} = \left(\frac{\text{CONTROL AAFE} - \text{TREATMENT AAFE}}{\text{CONTROL AAFE}} \right) \times 100$$

RESULTS

Table 1. Average number of adult houseflies recovered and percent efficacy for each treatment group.

		Study Day									
Treatment ¹		0	1	2	3	4	5	6	7	8	9
1 0.15 mg RMI-2011-C	Total Flies	163.00	55.00	107.00	58.00	85.00	17.00	31.00	15.00	23.00	30.00
	Avg. Flies	13.58	4.58	8.92	4.83	7.08	1.42	2.58	1.25	1.92	2.50
	% Efficacy ³	N/A	76.79	43.67	61.08	56.86	74.24	74.37	80.00	58.96	65.13
2 0.20 mg RMI-2011-C	Total Flies	184.00	93.00	5.00	9.00	12.00	2.00	1.00	3.00	15.00	5.00
	Avg. Flies	15.33	7.75	0.42	0.75	1.00	0.17	0.08	0.25	1.25	0.42
	% Efficacy ³	N/A	60.76	97.37	93.96	93.91	96.97	99.17	96.00	73.23	94.19
3 0.30 mg RMI-2011-C	Total Flies	162.00	125.00	1.00	6.00	5.00	0.00	12.00	7.00	4.00	2.00
	Avg. Flies	13.50	10.42	0.08	0.50	0.42	0.00	1.00	0.58	0.33	0.17
	% Efficacy ³	N/A	47.26	99.47	95.97	97.46	100.00	90.08	90.67	92.86	97.68
4 Untrt. Control ²	Total Flies	156.00	237.00	190.00	149.00	197.00	66.00	121.00	75.00	56.00	86.00
	Avg. Flies	13.00	19.75	15.83	12.42	16.42	5.50	10.08	6.25	4.67	7.17
	% Efficacy ³	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

¹ Treatment Groups 1, 2, and 3 were administered 0.15, 0.20, and 0.30 mg/kg/day of diflubenzuron formulated as 0.67% RMI-2011-C, respectively.

² Treatment Group 4 served as the untreated control group.

³ Percent efficacy calculated as: $\% \text{ Efficacy} = \frac{\text{Control AAFE} - \text{Treatment AAFE}}{\text{Control AAFE}} \times 100$

Study Author's Conclusions

Three 0.67% RMI-2011-C diflubenzuron formulation doses (0.15, 0.20, and 0.30 mg/kg/day) were administered to swine during this study. Decreases in successful house fly larval development and subsequent adult eclosion were observed on Day 1, with resultant efficacy values of 76.79, 60.76, and 47.26% for Treatment Groups 1, 2, and 3, respectively. Although the percent efficacy for Treatment Group 1 was substantially greater than that observed for Treatment Groups 2 and 3, subsequent values for this group varied greatly throughout the treatment period, with no value greater than 80% (Table 2). The percent efficacy observed for Treatment Groups 2 and 3 on Day 2 were 97 and 99%, respectively; values that remained consistent throughout the treatment period.

Reviewer's Conclusions

The results for the 0.20 and 0.30 mg dose groups gave acceptable results.

Reviewer's Recommendations

The study supports adding house flies to the label.

TASK 2 DATA EVALUATION RECORD

STUDY TYPE: Product Performance

MRID 493534-02. Pitzer, J.B. Final Report on Efficacy of Diflubenzuron Against Pest Flies Developing in Manure from Treated Animals 2. February 26, 2013.

OCSPP product performance guideline: Not given

Product Name: RMI-2011-B

EPA Reg. No. or File Symbol: 270-379

Decision number: 489559

DP number: 419844

Prepared for
Registration Division (7505)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, DC 20460

Prepared by
Summitec Corporation
Task Order No.: 2-202

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Disclaimer

This review may have been altered subsequent to the contractors' signatures above.

Summitec Corp. for the U.S. Environmental Protection Agency under Contract No. EP-W-11-014
